Claims:

1. A process for producing a pharmaceutical composition, which comprises:

(1) providing a plurality of containers;

(2) providing a plurality of excipient solutions;

(3) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;

(4) dispensing into each container at least one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, a property of each mixture being varied in different containers;

(5) incubating the mixture;

(6) determining onset of solid-state nucleation;

(7) selecting a pharmaceutical compound/excipient combination whereby onset of solid-state nucleation is retarded; and

(8) producing a pharmaceutical composition comprising the pharmaceutical compound/excipient combination.

2. A process according to claim 1, wherein the property varied in step (4) comprises identity or amount of the excipient or the pharmaceutical compound.

3. A process according to claim 1, wherein each solution comprises an aqueous solution.

4. A process according to claim 3, wherein the mixture simulates gastric juices or intestinal fluids.

5. A process according to claim 1, wherein the compound solution is supersaturated.

6. A process according to claim 1, wherein the plurality of containers are presented in a multiple well plate format.

7. A process according to claim 1, wherein at least the step of dispensing is performed with automated liquid handling apparatus.

8. A process according to claim 1, wherein the intimate mixture is formed using a mixer.

9. A process according to claim 1, wherein the step of incubating the mixture is preformed at constant temperature.

10. A process according to claim 9, wherein the temperature is approximately 37°C.

11. A process according to claim 1, wherein the onset of solid-state nucleation is determined by measuring the light scattering of the mixture.

12. A process according to claim 11, wherein the light scattering is measured using a nephelometer.

13. A process according to claim 1, which further comprises a step of determining the crystallinity of the product of solid-state nucleation before selecting the pharmaceutical compound/excipient combination.

14. A process according to claim 13, wherein the crystallinity is determined by birefringence screening.

15. A pharmaceutical composition obtained by a process according to claim 1.

16. A process for producing a pharmaceutical composition, which comprises:

(1) providing a plurality of containers;

(2) providing a plurality of excipient solutions;

(3) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;

(4) dispensing into each container one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, the excipient being varied in different containers;

(5) incubating the mixture;

(6) determining onset of solid-state nucleation;

(7) selecting an excipient which is found to retard onset of solid-state nucleation; and

(8) producing a pharmaceutical composition comprising the pharmaceutical compound and the selected excipient.

17. A pharmaceutical composition obtained by a process according to claim 16.

18. A method for assessing excipient-mediated retardation of solid-state nucleation of a pharmaceutical compound, which method comprises:

(1) providing a plurality of containers;

(2) providing a plurality of excipient solutions;

(3) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;

(4) dispensing into each container one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, a property of each mixture being varied in different containers;

(5) incubating the mixture;

(6) determining onset of solid-state nucleation; and

(7) ranking the property of the mixture according to time of onset of solid-state nucleation.

19. A method for screening excipients that retard solid-state nucleation of a pharmaceutical compound, which method comprises:

(1) providing a plurality of containers;

(2) providing a plurality of excipient solutions;

(3) providing a plurality of compound solutions, each having dissolved therein a pharmaceutical compound;

(4) dispensing into each container one of the excipient solutions with one of the compound solutions so as to form an intimate mixture, the excipient being varied in different containers;

(5) incubating the mixture;

(6) determining onset of solid-state nucleation; and

(7) ranking the excipient according to time of onset of solid-state nucleation.

20. A pharmaceutical composition comprising:

(a) a salt form of a drug having low solubility in gastric fluid conditions;

(b) a recrystallization/precipitation retardant; and

(c) a an optional enhancer;

wherein the composition retards recrystallization/precipitation of the drug for at least 5 minutes in gastric fluid conditions.

21. The pharmaceutical composition according to claim 20, wherein the recrystallization/precipitation retardant is a surfactant.

22. The pharmaceutical composition according to claim 21, wherein the surfactant has an interfacial tension of less than 10 dyne/cm or a surface tension of less then 42 dyne/cm.

23. The pharmaceutical composition according to claim 22, wherein the surfactant is a poloxamer.

24. The pharmaceutical composition according to claim 23, wherein the poloxamer has an interfacial tension of less than 10 dyne/cm or surface tension less then 42 dyne/cm.

25. The pharmaceutical composition according to claim 21, wherein the composition comprises an enhancer.

26. The pharmaceutical composition according to claim 22, wherein the composition comprises a cellulose ester as an enhancer.

27. The pharmaceutical composition according to claim 23, wherein the composition comprises HPC or HPMC as an enhancer.

28. The pharmaceutical composition according to claim 24, wherein the composition comprises HPC as an enhancer.

29. The composition according to claim 26, wherein recrystallization/precipitation is retarded for at least 10 minutes.

30. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 15 minutes.

31. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 20 minutes.

32. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 25 minutes.

33. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 30 minutes.

34. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 35 minutes.

35. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 40 minutes.

36. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 45 minutes.

37. The composition according to claim 29, wherein recrystallization/precipitation is retarded for at least 60 minutes.

38. The pharmaceutical composition according to claim 20, wherein the drug comprises a sulfonamide drug.

39. The pharmaceutical composition according to claim 38, wherein the sulfonamide drug is a benzene sulfonamide.

40. The pharmaceutical composition according to claim 39, wherein the benzene sulfonamide comprises celecoxib, deracoxib, valdecoxib, rofecoxib or eturicoxib.

41. The pharmaceutical composition according to claim 39, wherein the benzene sulfonamide is in the form of an alkali metal or alkaline earth metal salt.

42. The pharmaceutical composition according to claim 20, wherein the aqueous solubility of the drug is not more than 0.1mg/ml when measured at 37°C.

43. The pharmaceutical composition according to claim 20, wherein the aqueous solubility of the drug is not more than 10mg/ml when measured at 37°C.

44. A process for producing a pharmaceutical composition for delivering a supersaturated concentration of a drug having low aqueous solubility, which process comprises intimately mixing together components (a) (b) and (c) of claim 20.

45. The process according to claim 44, wherein the drug comprises a sulfonamide drug.

46. A process according to claim 45, wherein the sulfonamide drug is a benzene sulfonamide.

47. The process according to claim 46, wherein wherein the benzene sulfonamide comprises celecoxib, deracoxib, valdecoxib, rofecoxib or eturicoxib.

48. A process according to claim 47, wherein the benzene sulfonamide is in the form of an alkali metal or alkaline earth metal salt.

49. The process according to claim 44, wherein the aqueous solubility of the drug is not more than 0.1mg/ml when measured at 37°C.

50. The process according to claim 44, wherein the aqueous solubility of the drug is not more than 10mg/ml when measured at 37°C.

51. The pharmaceutical composition according to claim 20, wherein the salt is an alkali metal or alkaline earth metal salt.

52. The pharmaceutical composition according to claim 52, wherein the metal is sodium, potassium, lithium, calcium or magnesium.

53. The pharmaceutical composition according to claim 52, wherein the salt is crystalline.

54. The pharmaceutical composition according to claim 20, wherein:

(a) the bioavailability of the composition orally administered is at least 70%;

(b) the bioavailability of the composition orally administered is as least 80%;

(c) the bioavailability of the composition orally administered is as least 85%;

(d) the bioavailability of the composition orally administered is as least 90%;

(e) the bioavailability of the composition orally administered is as least 95%;

(f) the Cmax is at least 2 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(g) the Cmax is at least 3 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(h) the Cmax is at least 4 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(i) the Cmax is at least 5 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(j) the Cmax is at least 10 fold greater than a neutral form in vivo or in an in vitro dissolution assay; the Cmax is at least 2 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(k) the Cmax is at least 25 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(l) the Cmax is at least 50 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(m) the Cmax is at least 100 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(n) the Cmax is at least 250 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(o) the Cmax is at least 500 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(p) the Cmax is at least 750 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(q) the Cmax is at least 1000 fold greater than a neutral form in vivo or in an in vitro dissolution assay;

(r) the bioavailability of the composition is at least 50% greater than a neutral form;

(s) the bioavailability of the composition is at least 75% greater than a neutral form;

(t) the bioavailability of the composition is at least 2 fold that of a neutral form;

(u) the bioavailability of the composition is at least 3 fold that of a neutral form;

(v) the bioavailability of the composition is at least 4 fold that of a neutral form;

(w) the bioavailability of the composition is at least 5 fold that of a neutral form; or

(x) the bioavailability of the composition is at least 10 fold that of a neutral form.